Ref: 75.09.049US rev. 00

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IFU Cannula System

CAUTION
Federal law (USA) restricts this device to sale distribution and used by or on the order of physician.

ENGLISH Cannula System - INSTRUCTIONS FOR USE

Important notice: the device(s) can be prescribed and utilized only by a medical doctor legally authorized to perform this type of surgery.

GENERAL
Use of the instrumentation requires knowledge of the anatomy, biomechanics and reconstructive surgery of the locomotive system. The instrumentation can be used only by a qualified surgeon who practices with an awareness of current advances in science and surgical techniques. The user should ensure that the instruments are undamaged and in good working order before use. The user should also take all necessary precautions to avoid accidents (gloves, protective glasses, etc.).

PRODUCT DESCRIPTION
Medacta Cannula System includes a comprehensive choice of translucent threaded cannulas (available in multiple sizes), specifically designed for hip and shoulder arthroscopic procedures. The system is composed of the disposable threaded cannulas to be assembled with the dedicated disposable trocars. Hip instruments range contains also a metal set of reusable trocars and obturators.

The intended performance of each component of Medacta Cannula System is listed below:

- Trocar: facilitates the access to surgical site by puncturing the wall of the body cavity
- Cannula: provides stable access into the joint cavity inhibiting “fall-out” during instrument removal. The integrated stopcock valve aids fluid management. The shoulder cannula’s atraumatic tip prevents soft tissue and cartilage damage during insertion and use
- Hip Obturator: used with the dedicated hip metal trocar to prevent fluid diffusion. It is also used to enlarge access into the hip joint cavity guided by a guidewire Ø1.5 mm.

INTENDED USE:
The Medacta Cannula System is intended to maintain the portal distention of the joint while preventing fluid leakage and edema in the surrounding soft tissue. The portal facilitates the passage of instruments into the joint whilst performing hip or shoulder arthroscopic treatments.

POTENTIAL ADVERSE EFFECTS:

- Infection following the procedure
- Introduction of foreign materials can result in an inflammatory response or allergic reaction

WARNING

Check the expiration date for sterile single use instruments prior to use. Reutilizing them is strictly forbidden and would lead to unpredictable outcomes. Visually inspect the instruments after use in order to verify they did not experience any mechanical damage, which may cause release of particles in the human body. Any non-functional instrument should be immediately returned to Medacta® along with its label. The type of malfunction should be reported.

PRECAUTIONS

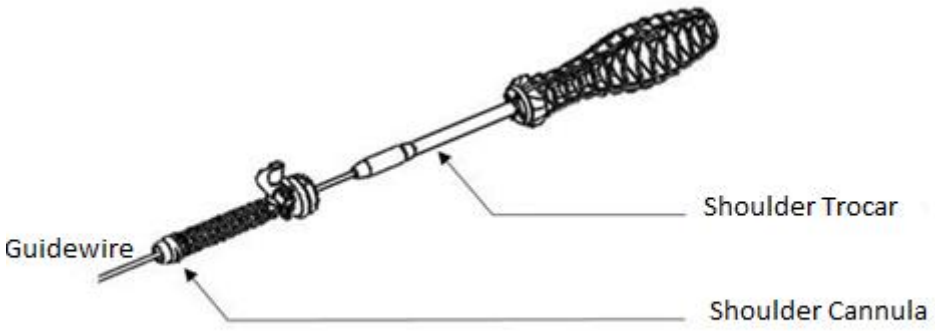
To avoid damaging Medacta Cannula System, do not use it with devices larger than the specified cannula diameter. Refer to Medacta Cannula System Product Catalogue (Ref. 99.103SM.180) to verify compatibility between Medacta Cannula System and Medacta hip/ shoulder instruments.

INSTRUCTIONS FOR USE

- Remove items form the sterile package using aseptic technique
- Prepare a portal following your preferred technique
- Introduce a Ø1.5 mm guidewire targeting the desired portal orientation and position

Shoulder Cannula System

Slide the cannulated trocar into the related cannula then insert the trocar onto the guidewire to access the shoulder joint. Slide the system onto the guidewire advancing it into the joint until the desired position is reached.

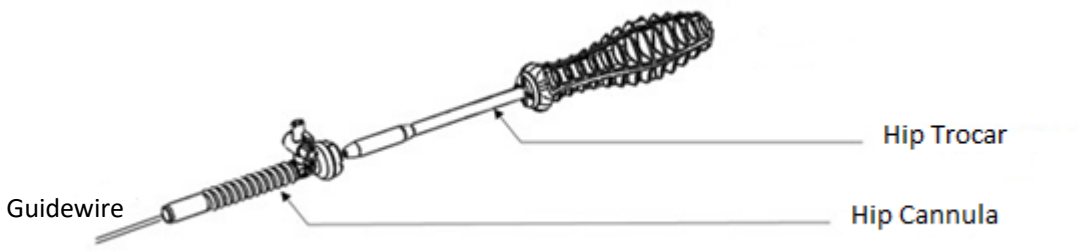


Ref. No.	Description	Materials
05.14.10.0001	Shoulder Cannula System Ø8.5x70mm	Pebax®; PC medical grade; PVC, Silicone Rubber
05.14.10.0002	Shoulder Cannula System Ø8.5x90mm	

Table 1 - Shoulder Cannula System

Hip Cannula System

Slide the cannulated trocar into the related cannula then insert the trocar onto the guidewire to access the hip joint. Slide the system onto the guidewire advancing it into the joint until the desired position is reached.

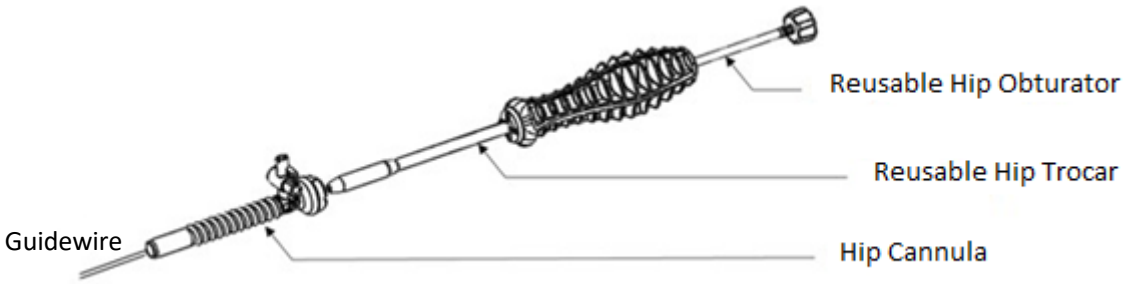


Ref. No.	Description	Materials
05.14.10.0020	Hip Cannula System Ø6.1x90mm	PC medical grade; PVC, Silicone Rubber
05.14.10.0021	Hip Cannula System Ø6.1x120mm	
05.14.10.0022	Hip Cannula System Ø8.5x90mm	
05.14.10.0023	Hip Cannula System Ø8.5x120mm	

Table 2 - Hip Cannula System

Hip Reusable Set

Select the reusable metal trocar (see table 3) of the corresponding diameter and length of the chosen hip disposable cannula (see table 4). Slide the cannulated trocar into the related cannula. Insert the reusable metal obturator of the corresponding length (see table 5) into the trocar. Slide the system onto the guidewire to access the hip joint. Advance it into the joint until the desired position is reached.



Ref. No.	Description	Materials
05.14.10.0010	Hip Metal Trocar Ø6.1x90mm	AISI 630, AISI 302-303, PROPILUX (dark blue)
05.14.10.0011	Hip Metal Trocar Ø6.1x120mm	
05.14.10.0015	Hip Metal Trocar Ø8.5x90mm	
05.01.10.0016	Hip Metal Trocar Ø8.5x120 mm	

Table 3 - Reusable Hip Metal Trocars

Ref. No.	Description	Materials
05.14.10.0005	Hip Cannula Ø6.1x90mm	PC medical grade; PVC, Silicone Rubber
05.14.10.0006	Hip Cannula Ø6.1x120mm	
05.14.10.0007	Hip Cannula Ø8.5x90mm	
05.14.10.0008	Hip Cannula Ø8.5x120mm	

Table 4 - Disposable Hip Cannulas compatible with Reusable Hip Metal Trocars

Ref. No.	Description	Materials
05.14.10.0030	Hip Obturator - Ø4x90 mm	AISI 630
05.14.10.0031	Hip Obturator - Ø4x120 mm	

Table 5 - Reusable Hip Obturators

To remove the cannula, retrieve it slowly via unscrewing until removed from the joint. Properly discard the cannula after use following facility guidelines.

PACKAGING

The Medacta Cannula System components are supplied sterile, in single use packages. The sterilization method is indicated on the label. The expiration date and package integrity must be checked to ensure the sterility of the contents has not been compromised. If the package is damaged, do no use the components.

STORAGE AND HANDLING

The packages should be stored in a cool, dry place, away from light. Handle with care.

TRADEMARKS

Medacta® is registered trademark of Medacta International SA, Castel San Pietro, Switzerland.

PICTOGRAMS

Date: 06/2019

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